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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,201	12/20/2001	Stephen Quirk	1443.027US1	1416
21186	7590	03/01/2005	EXAMINER	
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402			COUNTS, GARY W	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 03/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/027,201	Applicant(s) QUIRK, STEPHEN	
	Examiner Gary W. Counts	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>05/24/04, 05/01/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the claims

The amendment filed October 8, 2004 is acknowledged and has been entered. Further, upon reviewing the claims and after further consideration, claims 7-22 have been rejoined with claims 1-6. Thus, claims 1-22 are currently pending.

Information Disclosure Statement

In the Remarks section of the amendment filed October 8, 2004, the Applicant states that Applicant's Representatives have received copies of only pages 4 and 6 of the April 28, 2003 1449 form. After reviewing the IDS filed May 1, 2003 which was signed by Applicant's representative April 28, 2003. The IDS was comprised of sheets 1-3. Therefore, it is unclear what pages 4 and 6 Applicant is referring to. However, Examiner has attached the initialed 1-3 pages which were previously mailed to the Applicant. There are no pages 4-6 which were submitted in the IDS filed May 1, 2003.

Claim Objections

1. Claims 8-10 are objected to because of the following informalities: Claims 8-10 are considered duplicate claims because they depend from claim 6, which depends from claim 1. Claims 8-10 should depend from claim 7.
2. Claim 13 should depend from claim 7 because in order to be used in an immunoassay, the proteinoid microsphere would have to have a selective binding moiety as recited in claim 7.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 11, 13-15, 20 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 "the crosslinking agent" there is insufficient antecedent basis for this limitation. Perhaps Applicant intends for claim 11 to depend from claim 10.

Claims 13 and 15 provides for the use of labeled proteinoid microsphere, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 13 and 15 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim 14 "the immunoassay" there is insufficient antecedent basis for this limitation. Perhaps Applicant intends for claim 14 to depend from claim 13.

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Claim 20 "the acidic amino acid" there is insufficient antecedent basis for this limitation. Perhaps Applicant intends for claim 20 to depend from claim 18.

Claim 21 "the basic amino acid" there is insufficient antecedent basis for this limitation. Perhaps Applicant intends for claim 21 to depend from claim 18.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1, 5-8, and 12-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lohrmann et al (US 6,193,953) in view of Steiner et al (US 4,925,673).

Lohrmann et al disclose protein microparticles that can be comprised of chemically synthesized amino acid polymers (col 5, lines 40-57). Lohrmann et al disclose that the microparticles comprise chromium (label) linked to the microparticle

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(col 3, lines 39-42). Lohrmann et al also disclose that the microparticles can comprise a targeting moiety such as an antibody linked to the microparticle (col 13, lines 27-29).

Lohrmann et al differ from the instant invention in failing to specifically teach that the protein microparticle is a proteinoid microparticle.

Steiner et al discloses proteinoid microspheres (microparticles). Steiner et al discloses that the proteinoid microspheres are man made condensation polymers produced by random or directed assembly of natural or synthetic amino acids. Steiner et al disclose methods of producing the microspheres by using heat to condense the amino acids (see examples). Steiner et al disclose a mixture of amino acids comprising an acidic amino acid and a basic amino acid (col 5, lines 27-51).

It would have been obvious to one of ordinary skill in the art to synthesize the protein microparticles of Lohrmann et al using condensed amino acids such as taught by Steiner et al because Lohrmann et al specifically teaches that the protein microparticles can be comprised of synthesized amino acid polymers and Steiner et al specifically teaches that proteinoid microspheres are man made condensation polymers produced by random or directed assembly of synthetic amino acids. Therefore, one of ordinary skill in the art would have a reasonable expectation of success to form the protein microspheres of Lohrmann et al by condensing amino acids such as taught by Steiner et al. Therefore, the combination of Lohrmann et al and Steiner et al disclose proteinoid microspheres.

With respect to 5, 13-16 as recited in the instant claims. The claims are directed to intended use of the proteinoid microspheres and therefore are not given patentable

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weight. Further, since the combination of Lohrmann et al and Steiner et al disclose the claimed invention and the Applicant has not recited any structural differences over the prior art, the prior art is capable of performing the intended use.

8. Claims 2 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lohrmann et al in view of Steiner et al as applied to claims 1, 5-8, and 12-22 above, and further in view of Lee et al. (US 6,191,278)

See above for teachings of Lohrmann et al and Steiner et al.

Lohrmann et al and Steiner et al differ from the instant invention in failing to teach the label is rhodamine.

Lee et al disclose rhodamine dye reagents which can be used to label microspheres during their formation (col 4, lines 39-61). Lee et al discloses that the uses of these dyes labels can be used in a variety or biological and non-biological assays.

It would have been obvious to one of ordinary skill in the art to incorporate the use of rhodamine dye reagents as taught by Lee et al with the modified microspheres of Lohrmann et al because Lee et al teaches that rhodamine dye reagents can be used to label microspheres during their formation and further because Lee et al discloses that the uses of these dyes labels can be used in a variety or biological and non-biological assays, therefore a skilled artisan can have a reasonable expectation of success in incorporating the dye taught by Lee in the modified particles of Lohrmann et al.

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9. Claims 3, 4, 10, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lohrmann et al in view of Steiner et al as applied to claims 1, 5-8, and 12-22 above, and further in view of Mathiowitz et al (US 5,271,961).

See above for teachings of Lohrmann et al and Steiner et al.

Lohrmann et al and Steiner et al differ from the instant invention in failing to teach the proteinoid microsphere is formed by thermal condensation of a mixture of amino acids in the presence of a cross linking agent.

Mathiowitz et al disclose protein microspheres that can be modified. Mathiowitz et al disclose that the modification of the protein can be done by cross-linking the protein using agents such as glutataldehyde (col 6, lines 51-62). Mathiowitz et al disclose that such modifications provides a protein having enhanced or altered thermal stability, surface reactivity, molecular weight, charge and resistance to proteases (col 5, lines 50-56).

It would have been obvious to one of ordinary skill in the art to incorporate cross-linking as taught by Mathiowitz et al into the modified microspheres of Lohrmann et al because Mathiowitz et al shows that such modifications provides a protein having enhanced or altered thermal stability, surface reactivity, molecular weight, charge and resistance to proteases.

Response to Arguments

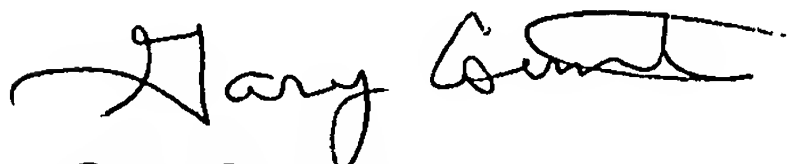
10. Applicant's arguments filed October 8, 2004 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

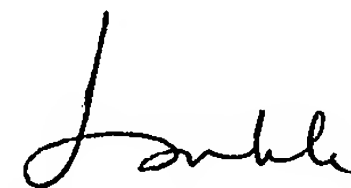
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gary Counts
Examiner
Art Unit 1641
February 23, 2005



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02/23/05